K083297

Section III - 510(k) Summary

Submitter:

JAN 28 2009

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7602 - Phone
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Wendy Garman - Contact Person

Date Summary Prepared: November 2008

Device Name:

- Trade Name – Pitt-Easy Dental Implant System
- Common Name – Endosseus Root-Form Implant
- Classification Name – Implant, Endosseous Dental, per 21 CFR § 872.3640

Devices for Which Substantial Equivalence is Claimed:

- Sybron Implant Solutions GmbH, *Pitt-Easy™ Dental Implant System, K053242*

Device Description:

The Pitt-Easy Dental Implant System is an endosseous dental implant that is intended to be surgically placed in bone of the upper or lower jaw arches to provide support for dental prosthesis. The Pitt-Easy Implant consists of two component parts: the implant (root component) and a threaded healing cap. In addition, attachments that are screw-retained, such as restorative abutments, are available for attachment to the root component.

Intended Use of the Device:

The Pitt-Easy Dental Implant System is indicated for use as an endosseous dental implant in the upper or lower jaw arches to provide support for prosthetic devices.

Substantial Equivalence:

There is no change in composition, design or intended use for the proposed device compared to its predicate and it is considered to be substantially equivalent. The only change being proposed is adding a new contraindication to the Directions for Use (DFU).. The new contraindication states that Pitt-Easy implants of 3.25mm diameter are not suitable for single tooth replacement in the posterior region.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sybron Implant Solutions GmbH
C/o Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporation
1717 West Collins Avenue
Orange, California 92867

JAN 2 8 2009

Re: K083297
Trade/Device Name: Pitt-Easy Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 19, 2009
Received: January 23, 2009

Dear Ms. Garman.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Labeling Change Being Effected
Sybron Dental Specialties, Inc.

Indications for Use

510(k) Number (if known):

Device Name: *Pitt-Easy Dental Implant System*

Indications For Use:

For use as an endosseous dental implant in the upper or lower jaw arches to provide support for prosthetic devices.

Contraindications for the Pitt-Easy 3.25 mm diameter implants are being added to the Directions for Use (DFU).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K033297